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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,567	03/26/2001	Kumar Subramanian	Kum13Sil.Lan	9915

7590

12/01/2003

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-2711

EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/01/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/817,567

Applicant(s)

SUBRAMANIAN ET AL.

Examiner

D. Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The Declaration filed on 9/8/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gertstein et al. reference. The Declaration was not signed as required to overcome the reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24-26 and 30-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisano et al. (US 5,928,207). Pisano discloses a microlancet device 20 for obtaining blood samples comprising an elongated single crystal silicon substrate having a base portion 24 and a penetration portion 22 and 40. The penetration portion has a sharp point 40. The width and thickness of the penetration portion narrow to become a sharp point.

Art Unit: 3731

The penetration portion of the device has a width cross-section of less than 700 and even less 300 micrometers, and a thickness less than 300 and even less than 150 micrometers (Col. 5, lines 5-11). As illustrated, the cross-section of the penetration end forms a sharp point. Also, the patent states that the device extends from a near infinitesimally small point to the maximum width and thickness dimensions. Hence, the penetration portion must at some point have a cross-section of about 50 micrometers in width and thickness, excluding the sharp point. As a result, the penetration portion extends from about 250 to about 50 micrometers in thickness and in width. The lancet is inherently disposable.

Claims 24, 25, 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Gartstein et al. (US 6,379,324). Illustrated in Fig. 21 (Figs. 18-21 illustrate the needle formation process), Gartstein disclose a microlancet device comprising an elongated single crystal silicon substrate 410 (Col. 14, lines 53-et seq.) having a base end 410 A,B, and a penetration end, which is the pointed portion of the lancet. They describe using chamber 470 to dispense medicine. However, it may also be used to receive a blood sample. Illustrated are cylindrically shaped needles, but tapered needles are also anticipated (Col. 17, lines 1-6). Tapered needles inherently have a chiseled shape. The device is inherently disposable.

Art Unit: 3731

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-29 and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisano et al. in view of Lin et al. (US 5,591,139). Pisano is silent regarding the length of the penetration portion. Nevertheless, Lin teaches a microlancet device for taking a blood sample wherein the needle is between about 1 and 6 millimeters (Col. 4, lines 11-14) to pierce the outer tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make Pisano's needle between about 1 and 6 millimeters as taught by Lin, in order to pierce the outer tissue and obtain a blood sample.

Pisano fails to disclose a silicon nitride layer of about 2000 angstroms thick. Nevertheless, Lin teaches in Fig. 3N-2 a silicon nitride film 64 used to cover the electrical contacts (Col. 5, lines 34-37). Pisano also discloses the use of electrical contacts. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a silicon nitride film of about 2000 angstroms to cover the electrical contacts.

Art Unit: 3731

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



DJD
November 26, 2003



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700